



Division of Clinical Laboratory Devices -- FDA Update



WHERE ARE WE NOW?

- ◆ People
- ◆ Performance
- ◆ Initiatives



PEOPLE

- ◆ Acting Commissioner
- ◆ New Chief Counsel
- ◆ Seasoned Center Director
- ◆ New Center Organization -- Linda Kahan
and Lillian Gill



PEOPLE

- ◆ Replacement for Peter Maxim -- Dr. Sousan Altaie
- ◆ Two relatively new branch chiefs -- Freddie Poole and Josie Bautista
- ◆ New genetics hires
- ◆ No growth pattern

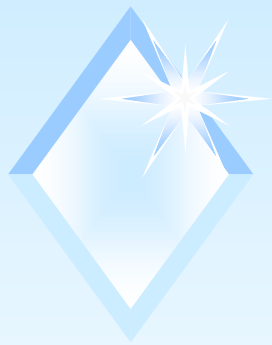


PERFORMANCE

◆ 510(k)s	↓	(868)
◆ PMAs	↑	(16)
◆ Protocol Reviews	↑	(74)

510(k)s -- 79 (90) days

PMAs -- 220 (180) days



INITIATIVES

- ◆ Down-classifications
 - ◆ Automated hematology analyzers
 - ◆ Rapid antimicrobial susceptibility tests
 - ◆ Cyclosporine/Tacrolimus



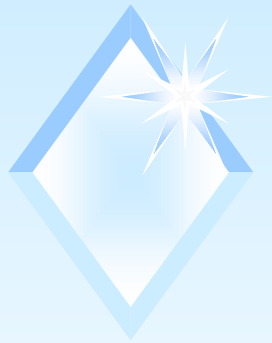
INITIATIVES

- ◆ Special Programs
 - ◆ CLIA complexity classification
 - ◆ Genetics initiatives
 - ◆ Bioterrorism preparedness
 - ◆ Antimicrobial resistance task force



INITIATIVES

- ◆ General Programs
 - ◆ Re-engineering
 - ◆ FDAMA
 - ◆ Strategic Plan



RE-ENGINEERING

- ◆ Administrative streamlining
- ◆ Increased menu of submission choices



Class II Products

- ◆ Traditional 510(k)
- ◆ Abbreviated 510(k)
- ◆ Special 510(k)
- ◆ 3rd Party Review



Class III Products

- ◆ Traditional PMA
- ◆ Modular PMA
- ◆ Product Development Protocol
- ◆ De Novo Classification



FDAMA

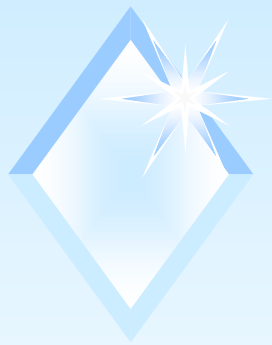
- ◆ Be Open
- ◆ Listen
- ◆ Be Interactive



LEAST BURDENSOME

◆ For **device effectiveness** in PMAs -

The Secretary shall consider, in consultation with the applicant, the least burdensome appropriate means of evaluating device effectiveness that would have a reasonable likelihood of resulting in approval



LEAST BURDENSOME

◆ For 510(k)s

The Secretary shall consider the least burdensome means of demonstrating substantial equivalence and request information accordingly



LEAST BURDENSOME

- ◆ Law
- ◆ Policy
- ◆ Practice
- ◆ Documents



WHERE ARE WE GOING?

STRATEGIC PLAN

VISION - Ensuring the health of the public throughout the Total Product Life Cycle - it's everybody's business



STRATEGIC GOALS

- ◆ Total Product Life Cycle
 - ◆ Concept to obsolescence/Seamless
- ◆ Magnet for Excellence
 - ◆ Attract Diverse Workforce
- ◆ Knowledge Management
 - ◆ *e*Center/**Leverage Knowledge Resources**
- ◆ Meaningful Metrics
 - ◆ Measure Impact on Public Health/Report Cards



IVD PILOT

- ◆ Unique consistency to IVD work
- ◆ Across offices, cadre of specialized workers
- ◆ Goal is to improve interactions
- ◆ Goal is to re-think processes for future



LEVERAGE RESOURCES

- ◆ Active interactions with government partners
- ◆ Industry Roundtable
- ◆ Professional Society Roundtable
- ◆ Pharmacogenomics Roundtable
- ◆ Improved Communication -- Convert Into Collaboration
- ◆ Good Science to Promote Public Health